eCGAP Focus Group

Date:	Tuesday, Aug.15, 2005
Time:	9 a.m. to 11 a.m.
Location:	Rockledge 1, Room 2198
Moderator:	Jennifer Flach
Next Meeting:	Tuesday, Sept. 6, 9 a.m. to 11a.m., Rockledge 1, Room 2198

Action Items

1. (Michael Goodman) Suggest to Grants.gov a wording change of question eight on the SBIR/STTR Information form.

2. (Sara Silver) Determine whether the following rule should be a warning or an exception: "Phase II must be submitted within 6 receipt dates after expiration of Phase I budget (project period end date)."

3. (Sara Silver) Meet with JoAnne Goodnight to determine the course of action for delineating between Phase I and Phase II forms.

4. (Mike Goodman) Check with Grants.gov whether a business rule can be changed to state that the first contract budget must be from the research institution

5. (Sara Silver) Set up warning if a Phase II application exists for a Phase I funded externally

Handouts

1. [SBIR/STTR Component for Grants.gov](#)

2. [SBIR/STTR Requirements and High-Level Business Processes](#)

SBIR/STTR Requirements

Sara started by passing out the SBIR/STTR information form on which Grants.gov is currently working. It will most likely be part of the 424RR form set, which will be required to submit all applications electronically, starting on the Dec. 1 receipt date. She also supplied a collection of requirements and high level business rules that correspond to the submission form. These requirements have been through one level of review so far and after this focus group meeting will undergo further evaluation as needed. She proceeded to go item by item through the business rules provided on the requirements list, so as to ensure accuracy. Group members agreed on the following updates and changes:

1. ***SBIR Form*** – Sara asked where this page should go within the grant image. Currently, it resides as a PHS 398-specific page, but it will eventually become a 424RR standard page. She reminded the group that the plan is to place the 424RR items before the PHS 398 forms. The best placement for this item will be as the first PHS 398 specific item. It will be independently bookmarked.

The group wondered whether or not this item should be viewable by reviewers. Tom Tatham stated that it is valuable for reviewers to see this item, so that they might discover any discrepancy that might arise within coding. Also, some of the answers might be important for reviewers to see in order for them to meet review requirements.

Tom wondered whether or not Question 8 on the information page would create the impression that applicants are required to submit their commercialization history if they have previous Phase II forms. Previously, this action was only required if the applicant had 15 or more Phase IIs. This is a Health and Human Services (HHS) requirement and should be clearly expressed as such on the form.

The group suggested changing the wording of this question so that the latter portion reads, "If yes, provide a company commercialization history *if required by* (instead of *in accordance with*) agency specific instructions using this attachment." Michael Goodman said that the wording has to stay as-is for now, because this form is in development, but he can *suggest* that the wording be changed so as to improve compliance.

Action: (Michael Goodman) Suggest to Grants.gov a wording change of question eight on the SBIR/STTR Information form.

2. *Identifying the Phase I Grant Number.* Phase II applications will require that the Phase I grant number be included in the Federal Identifier entry. The only numbers that the software will require are the IC and serial number. Whatever is provided by the applicant, however, must be parsed out and validated. This is an issue, because the Phase I work may have been funded by an agency other than NIH (or as an NIH contract), in which case the grant number may not be parsed. Sara will change the validation on this to a warning instead of an error.

3. *Cost Limitations* – These limitations will not be validated because of possible deviations. The 500k validations, which apply to R01s, do not apply to small business applications.

4. *Time Limitations* – These limitations will also not be validated.

5. *Limitations on Submitted Types* – With regard to the third bullet within this section (Phase II not submitted within 6 receipt dates after expiration of Phase I), there may be programmatic exceptions to the rule. Sara will make this a warning rather than a requirement. These business rules do allow for a Phase II competing continuation.

Action Item: (Sara Silver) Change the following rule to a warning (instead of an error): "Phase II must be submitted within 6 receipt dates after expiration of Phase I budget (project period end date)."

6. *Applicable Solicitations, Mechanisms and Receipt Dates* – These bullets do not apply to any specific application validations, but Sara wanted to go over them with the group.

7. *Required Attachments and Page Limitations* – The group suggested that the items referring to Fast Track applications be clarified to state that there is only one set of forms for Phase I and Phase II. These are not two separate pieces, and they should be consolidated. The applicant will need to be instructed to clearly show where Phase I ends and Phase II begins.

The group also agreed that, since personnel changes occur from Phase I to II, different environment and resource information should change accordingly.

CSR was concerned about this approach for Fast Track applications. Cross-referencing two different forms may make it very complicated and difficult for reviewers. Having separate budgets clarifies what the data entry has to be in IMPAC II. The budget needs to identify which phase a given year refers to. If this cannot be accomplished, there is a potential for major discrepancy. Also, the study section will sometimes decouple the fast track and score only the Phase I component. Phase I and Phase II plans must be definitively differentiated in order to facilitate proper scoring of each. Decoupling information, however, might lead to the loss of structured data.

There is a possibility of having two separate applications (Phase I and Phase II) and somehow combining them on the backend; however, one could also submit a resource as an attachment, making it the applicant's responsibility to delineate between Phases. In either possibility, applicants and reviewers must be able to understand what belongs to each Phase, respectively.

Tom Tatham explained the relationship between fast tracking and milestones. He said that at the end of Phase I, there have to be milestones that clearly illustrate deliverables and the way a Program Officer (PO) evaluates whether or not these deliverables were dealt with appropriately. The PO's resultant progress report after Phase I allows him or her to determine whether or not to fund Phase I and Phase II. One of the reasons a study section could decide only to fund Phase I is if clear milestones are not determined. At the very least, there should be a heading, which shows the separation between Phase I and Phase II. Mike Goodman stated that many of the proposed ideas are possible, but time constraints may prevent them from happening.

Group members finally decided to wait to follow up on all of these options with JoAnne Goodnight and determine the course of action at a later date. Sara will set up and attend this meeting and report back to the group.

Action: (Sara Silver) Meet with Joanne Goodnight to determine the course of action for delineating between Phase I and Phase II forms.

8. ***Budget Validations/Small Business and Consortium Budgets*** – Sometimes, the direct cost and total costs are not added correctly and are placed in the wrong categories. There will be validations on these additions.

9. ***STTR Relationship with Research Institution*** – Sara asked how to tell whether a budget is from a research institution as opposed to a consortium. Mike stated that there is no clear identification between these two forms. The business rule will state that the first sub-award budget in an STTR submission will be assumed to be for the research institution. Michael Goodman will check with Grants.gov to confirm that this assumption will be supported.

Action: (Mike Goodman) Check with Grants.gov whether NIH can assume that the first subaward budget that is included with the PureEdge submission will be in the first position in the transmission to NIH.

10. ***Letter to be Sent after Successful Processing***

11. *Checklist* – The group acknowledged the fact that this step is an opportunity to fix problems and establish validated small business codes.

12. *Prior Grant Validations*

Table Talk

Warning to indicate Phase II application exists—Sara mentioned the fact that there could be a Phase II application if a Phase I award was funded externally, either by another agency or by an intramural award granted somewhere within NIH. Group members admitted to having seen examples of this issue. There should be very few of these, but there should still be some sort of notification. Sara stated that a warning can be set up, or it could be sent to Receipt and Referral (R&R) and integrated with an Awaiting Receipt of Application (ARA) form. The group agreed that the warning would be sufficient and will only be left for the SBIR/STTR.

Action: (Sara Silver) Set up warning if a Phase II application exists for a Phase I funded externally

Publicity needed for electronic submission —Amy Swain voiced a concern that the message informing the community that electronic submissions will be mandatory for SBIR/STTR on December second is not big enough on the OER Small Business Funding Opportunities website (http://grants2.nih.gov/grants/funding/sbir.htm). Not only is the size insufficient, but it also only tells applicants to register in the Commons, which is only part of the process. Detailed notification about this shift should be widespread and displayed prominently.

Attendees

Diana Dixon (OD)	Jennifer Flach (OER)
Michael Goodman (OD)	Ellen Liberman (NEI)
JJ Maurer (IBM/Ekagra/OD	Steven Paugh (OD/LTS)
Sara Silver (IBM/Z-Tech Corp/OER)	Don Stallone (RSIS/OD)
Amy Swain (NCRR)	Thomas Tatham (CSR)
Janna Wehrle (NIGMS)	